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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/779,767	01/07/97	ZAGHOUBI	H ALLIA.143A

NED A ISRAELSON
KNOBBE MARTENS OLSON AND BEAR
16TH FLOOR
620 NEWPORT CENTER DRIVE
NEWPORT BEACH CA 92660

HM22/0929

EXAMINER
NULAN, F

ART UNIT	PAPER NUMBER
1644	

DATE MAILED:

09/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/79,767

Applicant(s)

Zab HOUANI

Examiner

NOLAN

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 6-29-99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 4-6, 9, 11-21, 24-27, 29-70 & 72-73 is/are pending in the application.
- Of the above claim(s) 5, 12-21, 25 and 30-65 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 4, 6, 9, 11, 24, 26, 27, 29, 66-70 & 72-73 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Part III DETAILED ACTION

1. Claims 4-6, 9, 11-21, 24-27, 29-70 and 72-73 are pending. Claims 5, 12-21, 25 and 30-65 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

2. The request filed on 6-29-99 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/779,767 is acceptable and a CPA has been established. An action on the CPA follows.

3. Since the following Office action presents only new grounds of rejection, Applicant's arguments are moot and not considered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 are rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (U) in view of Kuchroo et al. (U).

Bona et al., teaches compositions comprising an immunoglobulin with its CDR3 region replaced by a viral peptide, wherein said fusion protein is endocytosed by cells bearing an Fc receptor, processed by said cells and wherein said cell express said viral peptides, wherein said viral peptides are T cell peptides which specifically stimulate T cells (abstract, in particular).

The claimed invention differs from the prior art teachings by the recitations of using known T cell receptor antagonists derived from proteolipid. However, Kuchroo et al., teaches a known T cell receptor antagonist derived from myelin proteolipid protein (abstract, in particular). Kuchroo et al., also teaches that analogues derived from known autoimmune epitopes are useful in treating human autoimmune diseases because they compete with the original autoepitope in vivo (page 3330-3331, in particular). In addition Bona et al., teaches that using Immunoglobulins (IG's) replaced in the CDR3 region are useful in targeting antigens to antigen presenting cells because IG's have longer half lives than synthetic peptides, self-IG's are devoid of side effects and IG's are taken up by various types of APC's via Fc receptors (page 23 in particular). Bona et al., also teaches that the method of delivering antigens to cells via IG's "can be extended to express other biologically important epitopes such as tumor antigens, oncogenes or self antigens which can be used in the antitumor therapy or the therapy of autoimmune diseases. In the later cases, it is possible that the IG bearing epitopes of self antigens will be more efficient for peptide competition therapy envisioned as a novel immunotherapeutic approach of autoimmune diseases" (page 29, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute viral peptide-IG fusion compositions taught by Bona et al., for a known T cell receptor antagonist derived from the autoimmune protein myelin proteolipid taught by Kuchroo et al., because peptide-IG fusion compositions are better for delivery of antigens of interest because IG's have longer half lives than synthetic peptides, self-IG's are devoid of side effects and IG's are taken up by various types of APC's via Fc receptors (page 23 in particular), as taught by Bona et al., and said peptide-IG fusion compositions would be useful in the therapy of autoimmune diseases by delivery of peptides for competition therapy as taught by Bona et al., and because Kuchroo et al., teach the successful use of a peptide competitor, (i.e., an analogue) for treating experimental allergic encephalomyelitis, wherein said peptide is derived from myelin proteolipid protein. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

5. Claim 4, 6, 9, 11, 24, 26, 27, 29, 66-70 and 72-73 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is requested to cite page and line number in their originally filed claims or specification, for support of the term "known T cell receptor antagonist" recited in claim 66.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.



Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
September 27, 1999